Guidance for Industry

Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems

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Center for Devices and Radiological Health

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Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance (ending January 6, 2000), comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions may be submitted at any time for Agency consideration to, Tom M. Jakub. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Tom M. Jakub at 301 594-4591.

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Guidance[1] on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems

PURPOSE:

Manufacturers are required to disclose certain types of information, at cost, to assemblers to ensure that x-ray systems will meet federal performance standards. (21 Code of Federal Regulations sec. 1020.30 (g and h)) The information helps to ensure compliance with performance standards that reduce or maintain x-ray exposure to the patient and operator at the lowest possible level. Without specific performance standards and the required disclosure of specific information by the manufacturer to the assembler, there would be no control over diagnostic x-ray components or the x-ray systems. As the design features of x-ray systems and related major components advance, new questions have arisen about the scope of information the performance standard requires manufacturers to disclose, and whether computerization of that information affects the basic requirement or the cost.

BACKGROUND:

The Food and Drug Administration (FDA) protects the public health from unnecessary exposure to electronic product radiation by, among other things, requiring that electronic products meet performance standards. (See section 532 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii.)) Federal regulations require that manufacturers must provide assemblers and all others upon request, including secondary purchasers, information that is necessary to ensure the proper assembly, maintenance, and operation of x-ray equipment. This has been a long-standing and well-established federal requirement, which was announced on August 15, 1972, and became effective on August 15, 1973. (37 Fed. Reg. 16462, 16465)

Assembly of Components

Assembly procedures can affect compliance of a diagnostic x-ray system with federal performance standards. Accordingly, the manufacturing process is not complete until the

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

assembler has installed the component into the x-ray system, and the standard defines "manufacturer" to include "assembler." This means that the component manufacturer can certify only to a component's ability to function in compliance with the standard when the system is properly assembled and installed according to the manufacturer's instructions. A manufacturer's labeled certification of a component coupled with adequate and complete AIAT instructions will provide the assembler with all information necessary for the assembler to certify the component to the performance standard.

Installation of Components

The manufacturer must also provide instructions that describe how to install the assembled components so the unit meets applicable performance standards. In order to install components properly to become part of a system, the assembler must fix and align the relationship between the x-ray source and the related components of the diagnostic system. This activity will require adjustment and testing to ensure compliance with performance standards.

Legal Responsibility

Manufacturers and assemblers each bear legal responsibility for their roles in the manufacture and commerce of products subject to section 1020.30. See sections 535(e) and 538 of the act (21 U.S.C. 360ll(e), 360oo)). As a practical matter, close cooperation between the manufacturer and the assembler furthers the interests of both parties in avoiding legal liability for noncompliant or defective x-ray equipment.

GUIDANCE:

The manufacturer can certify only that the components or system manufactured meet the applicable federal performance standard if assembled and installed according to instructions. The assembler makes the final certification, as part of the final manufacture of the device, that the device complies with applicable performance standards. The assembler cannot be expected to know how to use all of the sophisticated and expensive test equipment needed to determine compliance; only that the system and its components were assembled, installed, adjusted, and tested, based on the manufacturer's instructions. Reliable certification, then, depends upon the manufacturer's provision to the assembler of adequate and complete instructions.

The scope of information that the manufacturer must provide includes instructions for assembly, installation, adjustment, and testing of x-ray components. (21 CFR 1020.30(g)) Technology and the configuration of x-ray systems have changed since the original information disclosure requirement was established by regulation in 1972. Consequently, people may be confused about the current meaning of the terms: assembly, installation, adjustment, and testing (AIAT).

The agency would like to explain the meaning of these four terms to help manufacturers and assemblers establish clear expectations about what information must be disclosed. As used in 1020.30(g), the meaning of assembly, installation, adjustment, and testing of diagnostic

x-ray units and their major components, and the examples of informational materials required under that provision, are as follows:

- **Assembly**: To fit together the parts or pieces of a component or system.

  Discussion: New x-ray components and accessories are shipped to a final destination in various boxes and crates. These components must be unpacked and re-assembled correctly before the unit can be used to make x-rays. The typical major component of a diagnostic x-ray system cannot simply be removed from the box and used by the operator. For example, various parts, such as printed circuit boards, and switches, may require assembly into the control console of a x-ray control unit in a medical facility. Assembly also includes the re-assembly of components that were not replaced but must be connected to the new component. Correct electrical and hardware connections with all of the equipment must be made before using the system. Such connections are considered assembly. Documentation or software programs that provide information or run automated instructions about what connections or reconnections are required for the system must be disclosed to the assembler.

  Software programs may involve assembly or re-assembly activity that does not need to be disclosed to the assembler. For example, the console's central processing unit may include unrevealed, protected software programs that create a log of assembly activities related to computer operations. Should the manufacturer wish to check the assembly history on a particular system, this log would provide information, independent of the assembler's report, about when activities occurred and perhaps about the identity of the replaced components. This information does not fall within the scope of the AIAT disclosure requirements.

  It is important to note that the term "assembly" and "installation" should not be used interchangeably. The term "installation" includes other activity not covered in the assembly activity.

- **Installation**: To set up for use by verifying that proper assembly and adjustments were made to assure compliance with federal performance specifications.

  Discussion: The unit may be used on humans once the installation is completed, in accordance with the manufacturer's instructions, which would include any additional adjustments and testing needed to verify compliance with performance specifications. For example, to complete the installation of a x-ray system, the assembler must combine (or assemble) the various certified components, e.g., tube housing assembly, beam-limiting device, and x-ray control, into an interdependent operating system. This means the assembler must make sure that the components work in coordination with each other and do not cause any of the components to

operate outside of applicable federal performance specifications, which are detailed in the regulations. (21 CFR 1020.30)

Documentation or software programs that provide information or instructions on how the various interdependent major components must be made compatible or aligned to meet applicable federal performance standards must be disclosed. However, a manufacturer may also have software programs that operate with specifications that are narrower than federal performance standards, which they use for internal quality assurance purposes. In addition, the firm may have developed a particular sequencing of installation that operates in conjunction with system accessories that do not directly or indirectly impact electronic radiation emissions. This information does not fall within the scope of AIAT disclosure requirements.

- **Adjustment**: To bring various component parts up to a true or more effective relative position for performance purposes.

  Discussion: Adjustment covers activities performed to make sure the components work interdependently within applicable federal performance standards. For example, the x-ray voltage applied to the x-ray tube has an associated accuracy specification, e.g., 100-kVp $\pm$ 5%. Information may be needed for the purchaser to determine his voltage regulation requirements. Adjustment often times must be made to the electrical circuitry to assure this performance specification is not exceeded. Calibration of the equipment's operational parameters is achieved by adjusting the electrical or mechanical features of the component.

  Documentation or software programs that provide information about what needs to be done or replaced to keep a machine operating within applicable performance standards must be disclosed. This would also include any required calibration references. However, the manufacturer may have incorporated a proprietary software program that continuously monitors the performance of the system and alerts the manufacturer if the system begins to look like it may need adjustment in the future, even though it is currently operating within the performance standard. This information does not fall within the scope of AIAT disclosure requirements.

- **Testing:** A critical examination, observation, or evaluation of such conditions or operations through testing procedures provided by the manufacturer that will prove the unit meets specifications.

  Discussion: The regulations define the performance requirements for diagnostic radiographic exposure reproducibility such that the coefficient of variation of radiation exposures shall not exceed 0.05. (See 21 CFR §1020.31(b)(1)) A test method for determining compliance with this performance standard is identified in the regulations. (See 21 CFR §1020.31(b)(2)) A test of x-ray equipment should produce data to verify the proper operation or performance of the x-ray system or

component. Other simple examples would be information on how to test for radiation leakage or proper beam alignment, particularly when a special technique is required due to the special design of the component or the complex beam alignment operations conducted through computer programs.

Documentation or basic software programs that address testing for applicable federal performance standards must be disclosed. However, the manufacturer may have additional enhanced software programs, with privileged access codes, that conduct the required tests more quickly to save time. The enhanced software programs may operate in conjunction with other proprietary accessories or functions, such as a daily test trend analysis that is relayed to the manufacturer in order to schedule advanced service calls. This helps the user avoid any interruption in the clinical use of the system. Such proprietary functions may increase the value of the system to the user, but the accessories and the software programs used in conjunction with these functions do not fall within the scope of AIAT for purposes of meeting applicable federal performance standards.

Manufacturers must provide all informational materials for installation, assembly, adjustment, and testing, as described above, regardless of the format in which those materials exist. Manufacturers may provide to assemblers and other members of the public hard copies of instructional software, so long as the package made generally available contains adequate, complete, and useable instructions for installation, assembly, adjustment, and testing.

Some manufacturers bundle software covered by 1020.30(g) with other types of software so the AIAT software cannot be extricated and provided separately to assemblers and other members of the public. Nothing in section 1020.30 prohibits this practice; however, the practice does not absolve manufacturers of their responsibilities under the performance standard to provide AIAT software at cost. Manufacturers who bundle their AIAT software with other software may comply with 1020.30(g) by providing the entire bundle at the cost of the AIAT software, as discussed below. Alternatively, the manufacturer may, by parceling the software domains, provide only the AIAT software to assemblers and others. Manufacturers may also satisfy the performance standard by providing printed materials, or by any other means that results in the provision of adequate, complete, and useable instructional materials.

Section 1020.30(g) provides that manufacturers may recover from assemblers and others only the "cost" of providing required instructional materials. Manufacturers should, in negotiation with purchasers, assemblers, and others, determine the dollar amount for any instructional package. Although private parties can and should set the exact price for materials provided under subsection (g), the performance standard establishes limits on what costs manufacturers may recover in determining that price.

The agency has explained that, for printed materials, manufacturers may charge the costs of producing each additional package or unit of instructions. The charge can reflect costs such as those for paper, labor, use of a copying machine, or other costs associated with each package the manufacturer must provide under the performance standard. Under this

interpretation, manufacturers should neither profit nor unfairly bear a loss by complying with section 1020.30(g). FDA believes the same principle should govern calculation of the costs for all materials required to be disclosed under 1020.30(g), whether printed, encoded in software, or otherwise presented. Although the question concerning cost has arisen primarily in the context of 1020.30(g), the same principle should also apply to the term "cost" elsewhere in 21 CFR Subchapter J, such as in sections 1020.30(h) and 1020.33(c).

For instructional materials encoded in software, the principle used to calculate the permissible charge for printed materials means that manufacturers may at least recover costs of man/hours, computer disks, and packaging materials used to produce each additional unit of instructional materials. The agency recognizes, however, that calculating the costs of producing each copy of a software program required by 1020.30(g) may require consideration of additional or different costs. For example, if a manufacturer licenses its instructional software from a developer, and must pay an additional fee for each unit licensed, it may be appropriate to permit the manufacturer to recover licensing fees for materials provided under 1020.30(g). This seems particularly relevant when the manufacturer cannot recover those costs in the price of its equipment or in some other way.

The public health need for AIAT information to be provided to assemblers and users since the Radiation Control for Health and Safety Act was passed in 1968 has not changed. If the information is not available, the public unknowingly may be exposed to unnecessary radiation hazards presented by electronic products. Without this information FDA, manufacturers, assemblers, users, and consumers could not make reasonable determinations or decisions associated with the safe and effective use of diagnostic x-ray systems and computed tomography components and systems in their health care.

For further information regarding compliance with the information disclosure requirements for diagnostic x-ray systems and their major component systems, please contact Thomas M. Jakub at 301 594-4591.